

**REMARKS**

The Office rejects claims 1-13, 16, and 17, and withdraws claims 14, 15, and 18-42 from consideration in the subject application. Applicant amends claims 1, 16, and 17, and cancels claim 5 without disclaimer or prejudice in the subject application. Claims 1-4 and 6-17 (2 independent claims; 16 total claims) remain pending in the application.

The Examiner acknowledges the election of claims 1-17 and the species "cells" and "accelerating the liquid drug". Since the species "decreasing the liquid drug" was not elected, the Examiner has withdrawn claims 14 and 15 from consideration.

Support for the various amendments may be found in the originally filed specification, claims, and figures. No new matter has been introduced by these amendments. Reconsideration of this application is respectfully requested.

**Double Patenting Rejection**

The Examiner provisionally rejects claims 1-13, 16, and 17 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-13, 16, and 17 of co-pending Application No. 10/954,639 ('639 Application).

The Examiner alleges that like the captioned application, claim 1 of the '639 Application claims a method for injecting a liquid drug containing a biological material into a subject at a predetermined range of velocity. The Examiner alleges that claim 6 of the '639 Application claims a method for injecting a liquid drug containing a biological material into a subject at an accelerated range. The Examiner alleges that the velocity ranges, diameters of the injector, and biological materials are the same in claims 2-5, 7-13, 16, and 17 of the '639 Application and claims 1-13, 16, and 17 of the captioned application.

Applicant has amended claims 1 and 17, so that claims 1 and 17 (and claims 2-4, 6-13, and 16, which variously depend from claim 1) are patentable over claims 1-13, 16, and 17 of '639 Application.

The '639 Application fails to claim "wherein the predetermined range of velocity is at least about 1 ml/min" as recited in claims 1 and 17 (and claims 2-4, 6-13, and 16, which variously depend from claim 1). Applicant respectfully requests withdrawal of this rejection.

**35 U.S.C. §112 REJECTION**

The Examiner rejects claim 16 under 35 U.S.C. §112 (second paragraph) as allegedly being indefinite.

The Examiner alleges that it is unclear what the phrase "prophylaxis of a heart" means. The Examiner alleges that, interpreted literally, "prophylaxis of a heart" appears to mean "prevention" of a heart. The Examiner requires further clarification of the meaning of "prophylaxis of a heart".

Applicant has amended claim 16 to clarify "prophylaxis of a heart" as "prophylaxis of a heart disease". For example, support for this amendment can be found at paragraphs [0124] and [0125] of the subject application (as published). Applicant requests withdrawal of this rejection.

**35 U.S.C. §102 REJECTION****Junior Reference**

The Examiner rejects claims 1-5 and 17 under 35 U.S.C. §102(b) as allegedly being anticipated by Junior (U.S. Patent No. 6,139,529, issued October 31, 2000, owned by the Inventor). Applicant respectfully traverses the rejection.

Applicant has canceled claim 5, so that the rejection of this claim is moot.

The Examiner alleges that Junior discloses the liquid drug can be injected into a tissue at a rate of less than 10 ml/min.

Junior discloses an advanced anesthetic method involving an apparatus for motorized injection of anesthetic liquids at a low and extended volumetric rate. Junior only discloses maintaining the anesthetic flow rate of approximately 0.3 ml/min, and more specifically, "at a maximum rate of 0.3 ml per minute".<sup>1</sup> Indeed, Junior teaches away from the claimed invention by specifying that uniformity of good performance in osseous or periosteous anesthetic application techniques results from injection of anesthetic "at a maximum rate of 0.3 ml per minute". As such, Junior sets an upper limit for the anesthetic flow rate, which falls outside the range of predetermined velocity recited in amended claims 1 and 17. Thus, Junior fails to disclose "wherein the predetermined range of velocity is at least about 1 ml/min" as recited in claims 1 and 17 (and claims 2-4, and 6, which variously depend from claim 1).

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<sup>1</sup> Junior, column 1, line 42, and column 2, lines 41-47.

Thus, Junior fails to disclose one or more claimed limitations, so that claims 1-4 and 17 are patentable over this reference.

#### Pokras Reference

The Examiner rejects claims 1, 2, 6, 7, and 17 under 35 U.S.C. §102(b) as allegedly being anticipated by Pokras (U.S. Patent No. 5,647,851, issued July 15, 1997, owned by the Inventor). Applicant respectfully traverses the rejection.

Pokras discloses a method and apparatus for vibrating an injection device using a threaded drive rod connected to a syringe plunger to drive the plunger at a predetermined rate to expel the medication through the needle at a measured rate.<sup>2</sup> The vibration serves to enhance the rate at which the fluid migrates anesthetic into the tissue; thus, accelerating disbursement of the anesthetic to the site of interest and minimizing the pain inflicted by the injection process.<sup>3</sup>

But Pokras fails to disclose "wherein the predetermined range of velocity is at least about 1 ml/min" as recited in claims 1 and 17 (and claims 2, 6, and 7, which variously depend from claim 1).

Thus, Pokras fails to disclose one or more claimed limitations, so that claims 1, 2, 6, 7, and 17 are patentable over this reference.

#### 35 U.S.C. §103 REJECTION

The Examiner rejects claims 1-13, 16, and 17 under 35 U.S.C. §103(a) as allegedly being unpatentable over Ben Haim (WO 99/39624, published February 5, 1998, assignee is BIOSENSE INC.) in view of Edge (U.S. Patent No. 6,673,604, issued January 6, 2004, assignee is Diacrin, Inc.). Applicant respectfully traverses the rejection.

Applicant has canceled claim 5, so that the rejection of this claim is moot.

Ben Haim discloses methods and devices for an accurate placement of drug delivery devices using a catheter.<sup>4</sup> The catheter has a position sensor (which generates signals responsive to the position of the catheter) and a drug delivery device (which administers a desired dose of a therapeutic drug at the site determined responsive to the signals from the position sensor).<sup>5</sup>

<sup>2</sup> Pokras, column 3, lines 13-17.

<sup>3</sup> Pokras, column 9, lines 40-47.

<sup>4</sup> Ben Haim, page 4, lines 10-23.

<sup>5</sup> Ben Haim, page 10, lines 9-12.

As such, Ben Haim is mainly for proper "placement" of drugs. On the contrary, the claimed invention provides a method for injecting a liquid drug at a predetermined range of velocity. Ben Haim fails to teach, advise, or suggest "wherein the predetermined range of velocity is at least about 1 ml/min" as recited in claims 1 and 17 (and claims 2-4, 6-13, and 16, which variously depend from claim 1).

The Edge reference merely discloses administering skeletal myoblasts to a subject having disorders characterized by insufficient cardiac function.<sup>6</sup> But Edge fails to teach, advise, or suggest "wherein the predetermined range of velocity is at least about 1 ml/min" as recited in claims 1 and 17 (and claims 2-4, 6-13, and 16, which variously depend from claim 1).

Furthermore, one exemplary advantage of the claimed invention is the discovery that difficulties in implanting cells or introducing genes without damaging the cells or the genes (for example) can be solved unexpectedly by injecting biological material into an organism at a maintained predetermined range of velocity.<sup>7</sup> But Ben Haim and Edge fail to recognize this advantage, and consequently, fail to address it.

Thus, Ben Haim in view of Edge fails to teach, advise, or suggest one or more claimed limitations, so that claims 1-4, 6-13, 16, and 17 are patentable over these references.

<sup>6</sup> Edge, Abstract and column 1, line 66 to column 2, line 2.

<sup>7</sup> Subject Application (as published), paragraphs [0008] and [0012].

CONCLUSION

Thus, the Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the application is thus requested. Applicant invites the Office to telephone the undersigned if he or she has any questions whatsoever regarding this Response or the present application in general.

Respectfully submitted,

Date: 2-27-06

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